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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,953

03/26/2004

Herman Van Mellaert

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02/03/2006

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/809,953

Applicant(s)

VAN MELLAERT ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 20,23 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 21,22,24-27 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 21-22, 24-27 and 32) in the reply filed on 17 November 2005 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden to search both the protein and the DNA. This is not found persuasive because a search of the protein and the DNA requires searches of different sequence databases, which is a serious burden on PTO resources.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20, 23 and 28-31 are withdrawn from consideration, as being drawn to a non-elected invention.

2. The abstract is not descriptive of the instant invention, which is a DNA encoding a Bt14 protein, chimeric genes, plant, seeds and plant cells comprising it, and a method of using it to control insects. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

3. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of controlling insects comprising growing plants or seeds transformed with a nucleic acid encoding a Bt14 endotoxin, does not reasonably provide enablement for a method of controlling insects comprising growing plant cells transformed with a nucleic acid encoding a Bt14 endotoxin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of controlling insects comprising growing plants, seeds or plant cells transformed with a nucleic acid encoding a Bt14 endotoxin

The instant specification, however, only provides guidance for transforming tobacco plants with a nucleic acid encoding a Bt14 endotoxin.

The instant specification fails to provide guidance for a method of controlling insects comprising growing plant cells transformed with a nucleic acid encoding a Bt14 endotoxin. Plant cells alone would not survive outside the laboratory setting; thus, this method has no real world use.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 21-22, 24-25 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 21 is indefinite for being dependent upon a non-elected claim.

Claim 21 lacks antecedent basis for the limitation "protein fragment of claim 20".

Claim 22 lacks antecedent basis for the limitation "the TTG start codon".

Claim 24 lacks antecedent basis for the limitation "the DNA of claim 21".

Claim 25 lacks antecedent basis for the limitation "the DNA of claim 22".

Claim 32 lacks antecedent basis for the limitation "the plant, seed or plant cell of claim 25."

Claim 32 is indefinite because it lacks agreement between the preamble of the method and the positive method steps. Methods must be circular; the final step must generate the item the method is intended to produce. The method of controlling insects ends in growing plants, seeds or plant cells transformed with a nucleic acid encoding a Bt14 endotoxin, when it should end in the control of insects.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Brizzard et al (1988, Nuc. Acids Res. 16:4168-4169).

Brizzard et al teach a nucleic acid encoding cryA4, which is Bt14 in the nomenclature of the instant application (see pg 28, paragraph 1 of the specification).

10. Claims 21, 24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Rangan (US Patent 5,244,802, filed November 1987).

Rangan teaches cotton plant cells transformed with a nucleic acid encoding a Bt14 Bacillus thuriangiensis endotoxin fragment (column 17, line 1, to column 24, line 45).

### *Double Patenting*

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 21-22, 24-27 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 22 of U.S. Patent No. 6,172,281. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the isolated DNA encoding Bt14 of the instant claims is essential to the method of transforming plants with at least two nucleic acids, one of which encodes Bt14 and the transgenic plants thereby obtained, of the issued patent. Thus, the instantly claimed DNA is obvious in view of the claims of the issued patent. Additionally, because the Bt14 protein is produced in the plants of the issued patent, a chimeric gene comprising a nucleic acid encoding Bt14 operably linked to a promoter that can direct expression in plant cells must have been used, making the DNA molecule of claim 22 of the instant application obvious.

13. Claims 21-22, 24-27 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-15 of U.S. Patent No. 5,866,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because the plants of the issued patent have been transformed with at least two nucleic acids, one of which encodes Bt14; thus, the plants of the instant application, which have been transformed with at a nucleic acid encoding Bt14, are obvious. Additionally, because the Bt14 protein is produced in the plants of the issued patent, a chimeric gene comprising a nucleic acid encoding Bt14 operably linked to a promoter that can direct expression in plant cells must have been used, making the DNA molecule of claims 22 and 24-25 of the instant application obvious.

14. Claims 21-22, 24-27 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,855,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patent are drawn to a nucleic acid encoding the Bt protein SEQ ID NO:10, which is a species of the genus of all the nucleic acids encoding the Bt proteins, as

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claimed in the instant application. Furthermore, SEQ ID NO:9, as claimed in the issued patent, a nucleic acid in which the TTG start codon has been replaced with ATG. The claims of the issued patent are also drawn to chimeric genes, plants, seeds or plant cells comprising the nucleic acid, and are thus species of the genus of chimeric genes, plants, seeds or plant cells comprising the nucleic acid, as claimed in the instant application. As the method of controlling insects, as claimed in the instant application, only comprises growing the plants, seeds, or plant cells, the method is anticipated by the instant application.

### *Conclusion*

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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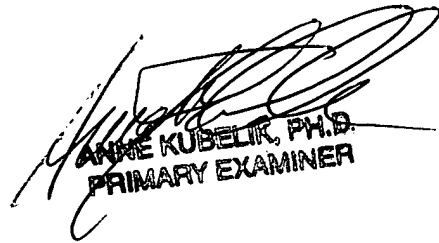
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Anne Kubelik, Ph.D.  
January 30, 2006



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER